

REMARKS

This paper is filed in response to the Office Action mailed September 26, 2006. Claims 1 to 76 are pending. Claims 10, 12 to 14, 21, 22 and 40 to 68 stand withdrawn for consideration as directed to a non-elected invention. Claims 1 to 9, 11, 15 to 20, 23 to 39 and 69 to 76 are therefore under consideration.

Regarding the Amendments

The specification has been amended to recite a new title. The amendment was made in response to the Examiner's request and, therefore, addresses an informality. Accordingly, no new matter has been added and entry of the amendment to the specification is respectfully requested.

The amendments to claims 71 and 72 are supported throughout the specification. In particular, the amendment to claim 71 to recite that the method is directed to "treating" asthma is supported, for example, by originally filed claims 15, 16, 23, 24 and 34 to 37. The amendment to claim 72 to recite that the method is directed to "reducing or inhibiting" a recall response associated with asthma is supported, for example, by originally filed claims 1, 5 to 7 and 70. Accordingly, as the amendments to claims 71 and 72 are supported by the specification no new matter has been added and entry thereof is respectfully requested.

Regarding the Priority Provisional Application

The Examiner has indicated that the priority provisional application, 60/410,534, provides adequate support under 35 U.S.C. §112, for the subject matter claimed. Applicants wish to thank the Examiner for acknowledging that priority provisional application, 60/410,534, provides adequate support under 35 U.S.C. §112, for the subject matter claimed.

Regarding the Declaration

The Examiner has indicated that the Oath or Declaration is defective. Applicants respectfully point out that a Declaration is not considered defective if an inventor does not

provide a date of execution. [M.P.E.P. §§602.03 and 602.05] Consequently, Applicants need not submit a Supplemental Declaration.

Regarding the Declaration

The Examiner has indicated that the title is not descriptive. Applicants have amended the title as set forth above, and believe that the title is descriptive.

Regarding the IDS

The Examiner has indicated that the IDS filed June 13, 2005, has been acknowledged. Applicants wish to thank the Examiner for acknowledging that the references filed in the IDS have been considered.

I. REJECTION UNDER 35 U.S.C. §112

The rejection of claims 71 and 72 under 35 U.S.C. §112, first paragraph as allegedly lacking enablement is respectfully traversed. The Examiner indicates that the specification allegedly “does not provide sufficient enabling description of.....‘preventing’ asthma or recall response associated with asthma.” [pages 4 and 5 of the Office Action]

Claims 71 and 72 are adequately enabled under 35 U.S.C. §112, first paragraph. Nevertheless, solely in order to further prosecution of the application, and without acquiescing to the propriety of the rejection, claims 71 and 72 have been amended to delete the term “preventing.” In view of the amendment, the grounds for rejection are moot and Applicants respectfully request that the rejection under 35 U.S.C. §112, first paragraph, be withdrawn.

II. REJECTIONS UNDER 35 U.S.C. §§102(e) and 103(a)

The rejection of claims 1 to 9, 15 to 20, 23 to 39 and 69 to 76 under 35 U.S.C. §102(e) as allegedly anticipated by Arndt *et al.* (U.S. Patent Publication No. 2004/0009174) is respectfully traversed. Allegedly, Arndt *et al.* teaches each and every element of the claimed methods.

Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration *In re Spada*, 911 F.2d 705 (Fed. Cir. 1990), *In re Bond*, 910 F.2d 831 (Fed. Cir. 1990).

Claims 1 to 9, 15 to 20, 23 to 39 and 69 to 76 are not anticipated by Arndt *et al.* (U.S. Patent Publication No. 2004/0009174). Nevertheless, solely in order to further prosecution of the application and without acquiescing to the propriety of the rejection, submitted herewith is a Declaration under 37 C.F.R. §1.131, executed by Drs. Michael Croft and Shahram Salek-Ardakani, the inventors of the application, and four laboratory notebook pages (Exhibit A, pages 1 to 4). In the Declaration, the inventors state that they were diligent from the time claims 1 to 9, 11, 15 to 20, 23 to 39, and 69 to 76, were conceived prior to the December 18, 2001, filing date of the priority application of Arndt *et al.* (Application Serial No. 60/341,453), and up until the September 11, 2002, filing of provisional patent application serial no. 60/410,534, to which this application claims priority (Declaration, paragraph 5).

Evidence of conception is indicated in Exhibit A, four pages from the inventors' laboratory notebooks, each of which is labeled 1 to 4 (Declaration, paragraph 6). These pages include a description of studies and results of mice sensitized with an antigen which were then treated with an anti-OX40L antibody after the animals received a subsequent antigen challenge in a recall immune response.

Three groups of four mice (BL/6) each were immunized with OVA/Alum at day 0 (Declaration, paragraph 7, Exhibit A, page 1). Following immunization, mice were administered either control IgG for 3 days at days 24-27, anti-OX40L antibody for 3 days at days 24-27, or anti-OX40L antibody for 4 days at days 27-31 (Declaration, paragraph 7, Exhibit A, page 1). Mice were then challenged via the airways in a recall immune response with OVA delivered for 30 minutes each day at days 28-31.

To ascertain lung inflammation, IL-4, IFN, IL-5 and IgE, were measured in lung lavages. IL-4 was reduced by an average of approximately 4-fold in the anti-OX40L antibody treated mice, compared to control mice (Declaration, paragraph 8, Exhibit A, pages 2 and 4). IgE levels were also reduced in anti-OX40L antibody treated mice, compared to control mice (Declaration, paragraph 8, Exhibit A, pages 2 and 4). The inventors therefore conclude that these studies indicate that anti-OX40L antibody reduces clinical indicia of asthma.

Neutrophil, eosinophil, monocyte and lymphocyte numbers were also measured in lung lavages. Eosinophils were reduced in the lung of anti-OX40L antibody treated mice compared to control mice (Declaration, paragraph 9, Exhibit A, pages 3 and 4). Lymphocytes were also

reduced by an average of approximately 6-fold in the lung of anti-OX40L antibody treated mice compared to control mice (Declaration, paragraph 9, Exhibit A, pages 3 and 4). The inventors therefore conclude that anti-OX40L antibody reduces eosinophil and lymphocyte infiltration of lung associated with asthma.

In view of the Declaration under 37 C.F.R. §1.131, by Drs. Michael Croft and Shahram Salek-Ardakani, and accompanying four laboratory notebook pages (Exhibit A) indicating that claims 1 to 9, 11, 15 to 20, 23 to 39, and 69 to 76, were conceived prior to the December 18, 2001, filing date of the priority application of Arndt *et al.* (Application Serial No. 60/341,453), and that the inventors were diligent up until the September 11, 2002, filing of priority provisional patent application serial no. 60/410,534, Arndt *et al.* (U.S. Patent Publication No. 2004/0009174) is not available as prior art under 35 U.S.C. §102 against claims 1 to 9, 11, 15 to 20, 23 to 39, and 69 to 76. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §102(e), be withdrawn.

The rejection of claims 1, 8 and 11 under 35 U.S.C. §103(a) as allegedly unpatentable over Arndt *et al.* in view of Owens *et al.* (J. Immunol. Methods 168:149 (1994)) is respectfully traversed. Allegedly, claims 1, 8 and 11 would have been obvious to one of ordinary skill in the art in view of Arndt *et al.* and Owens *et al.*

Claims 1, 8 and 11 would not have been obvious in view of Arndt *et al.* and Owens *et al.* at the time of the invention. Nevertheless, solely in order to further prosecution of the application and without acquiescing to the propriety of the rejection, the Declaration under 37 C.F.R. §1.131, executed by Drs. Michael Croft and Shahram Salek-Ardakani, and accompanying four laboratory notebook pages (Exhibit A, pages 1 to 4) submitted herewith indicates that claims 1 to 9, 11, 15 to 20, 23 to 39, and 69 to 76, were conceived prior to the December 18, 2001, filing date of the priority application of Arndt *et al.* (Application Serial No. 60/341,453), and that the inventors were diligent up until the September 11, 2002, filing of priority provisional patent application serial no. 60/410,534. Consequently, Arndt *et al.* (U.S. Patent Publication No. 2004/0009174) is not available as prior art under 35 U.S.C. §103 against claims 1, 8 and 11. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §103(a) be withdrawn.

CONCLUSION

In summary, for the reasons set forth herein, Applicants maintain that claims 1 to 9, 11, 15 to 20, 23 to 39 and 69 to 76 clearly and patentably define the invention, respectfully request that the Examiner reconsider the various grounds set forth in the Office Action, and respectfully request the allowance of the claims which are now pending.

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicant's representative can be reached at (858) 509-4065.

Please charge any fees associated with the submission of this paper to Deposit Account Number 03-3975. The Commissioner for Patents is also authorized to credit any over payments to the above-referenced Deposit Account.

Respectfully submitted,

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CERTIFICATION UNDER 37 C.F.R. §§ 1.8 and/or 1.10*

(When using Express Mail, the Express Mail label number is *mandatory*; Express Mail certification is *optional*.)

I hereby certify that, on the date shown below, this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: March 23, 2006



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* Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.